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FILING DATE APPLICATION NO. FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/527,788 11/02/2005 Sabine Wolf 63047(45107) 7480 7590 12/03/2007 **EXAMINER** EDWARDS ANGELL PALMER & DODGE LLP STEELE, AMBER D P.O. BOX 55874 BOSTON, MA 02205 ART UNIT PAPER NUMBER 1639 MAIL DATE **DELIVERY MODE** 12/03/2007 **PAPER**

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/527,788	WOLF ET AL.
	Examiner	Art Unit
	Amber D. Steele	1639
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status		
1) Responsive to communication(s) filed on	_•	
2a) This action is FINAL . 2b) This	action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>1-13,16,17 and 21-26</u> is/are pending in the application.		
4a) Of the above claim(s) is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) 1-13,16,17 and 21-26 are subject to restriction and/or election requirement.		
Application Papers		
9) The specification is objected to by the Examiner.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received.		
2. Certified copies of the priority documents have been received in Application No3. Copies of the certified copies of the priority documents have been received in this National Stage		
application from the International Bureau (PCT Rule 17.2(a)).		
* See the attached detailed Office action for a list of the certified copies not received.		
Attachment(s)		(DTO 440)
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail D	
3) Information Disclosure Statement(s) (PTO/SB/08)	5) 🔲 Notice of Informal F	
Paper No(s)/Mail Date	6) Other:	

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DETAILED ACTION

Status of the Claims

1. The preliminary amendment to the claims received on March 11, 2005 amended claims 2-13 and 16-17, canceled claims 14-15 and 18-20, and added new claims 21-26.

Claims 1-13, 16-17, and 21-26 are currently pending and under consideration.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 21, drawn to a method for identifying the presence of a blood brain barrier (BBB) specific protein via a subtractive DNA library.

Group II, claim(s) 7-8, drawn to a BBB specific protein of SEQ ID NO: 5.

Group III, claim(s) 7-8, drawn to a BBB specific protein of SEQ ID NO: 14.

Group IV, claim(s) 7-8, drawn to a BBB specific protein of SEQ ID NO: 19.

Group V, claim(s) 7-8, drawn to a BBB specific protein of SEQ ID NO: 53.

Group VI, claim(s) 9-11, drawn to a method for identifying the presence of a BBB specific protein via isoelectric focusing.

Group VII, claim(s) 12-13, drawn to a BBB specific protein of SEQ ID NO: 23.

Group VIII, claim(s) 12-13, drawn to a BBB specific protein of SEQ ID NO: 27.

Group IX, claim(s) 12-13, drawn to a BBB specific protein of SEQ ID NO: 33.

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Group X, claim(s) 16-17, drawn to a BBB specific agent (i.e. protein).

Group XI, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 4.

Group XII, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 6.

Group XIII, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 15.

Group XIV, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 22.

Group XV, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 23.

Group XVI, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 26.

Group XVII, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 32.

Group XVIII, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 35.

Group XIX, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 36.

Group XX, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 43.

Group XXI, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 49.

Group XXII, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 52.

Group XXIII, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 54.

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Group XXIV, claim(s) 22-24, drawn to a method for diagnosis using a BBB specific protein of SEQ ID NO: 55.

Group XXV, claim(s) 25, drawn to a method for transporting a substance using a BBB specific protein.

Group XXVI, claim(s) 26, drawn to a method of diagnosis using a BBB specific protein.

3. The inventions listed as Groups I-XXVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature is a BBB specific protein which is known in the art. In addition, the various SEQ ID NOs: of Groups II-V, VII-IX, and XI-XXIV do not share a common core structure and thus do not have a common technical feature.

Specifically, Kozarich et al. U.S. Patent 5,268,164 teach poplypeptides called receptor mediated permeabilizers (RMP) that increase the permeability of the blood brain barrier (BBB) and methods of making RMPs (please refer to the entire specification particularly the abstract; columns 2 and 4; and Examples). In addition, Kozarich et al. teach polypeptides with a core structure of SEQ ID NO: 1 and bradykinin analogues (i.e. A-7; please refer to column 2). Furthermore, Kozarich et al. teach that the RMPs are specific for B₂ receptors located on the surface of brain endothelial cells that form the blood brain barrier (please refer to column 4).

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4. Applicant is advised that the reply to this requirement to be complete must include (i) an

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election of a species or invention to be examined even though the requirement be traversed (37

CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

5. The election of an invention or species may be made with or without traverse. To reserve

a right to petition, the election must be made with traverse. If the reply does not distinctly and

specifically point out supposed errors in the restriction requirement, the election shall be treated

as an election without traverse.

6. Should applicant traverse on the ground that the inventions or species are not patentably

distinct, applicant should submit evidence or identify such evidence now of record showing the

inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the

evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the

inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR

1.48(b) and by the fee required under 37 CFR 1.17(i).

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Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/ Patent Examiner AU1639

November 26, 2007-